

475610 1/10/15

STIC-ILL

From: STIC-Biotech/ChemLib
Sent: Monday, December 15, 2003 3:13 PM
To: STIC-ILL
Subject: FW: In re: 10018373 Please supply the following journal articles:

-----Original Message-----

From: Ford, Vanessa
Sent: Monday, December 15, 2003 3:06 PM
To: STIC-Biotech/ChemLib
Subject: In re: 10018373 Please supply the following journal articles:

Dermatol Surg. 1997 Dec;23(12):1221-2.

Lancet. 1997 Jan 25;349(9047):252.

Int J Dermatol. 1999 Sep;38(9):641-55.

Ann Pharmacother. 1998 Dec;32(12):1365-7.

Arch Dermatol. 1998, 134:301-4.

Clin. Exp. Dermatol., 1996, 21:276-8.

J Am Acad Dermatol., 1998, 28:227-9.

Vanessa L. Ford
Biotechnology Patent Examiner
Office: CM1 8A16
Mailbox: CM1 8E12
Phone: 703.308.4735
Art unit:1645

12555511

STIC-ILL

475611 NO 12/15

From: STIC-Biotech/ChemLib
S nt: Monday, December 15, 2003 3:13 PM
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Biotechnology Patent Examiner
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Art unit:1645

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STIC-ILL

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NPL
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Clin. Exp. Dermatol., 1996, 21:276-8.

J Am Acad Dermatol., 1998, 28:227-9.

Vanessa L. Ford
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Art unit:1645

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STIC-ILL

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From: STIC-Biotech/ChemLib
Sent: Monday, December 15, 2003 3:41 PM
To: STIC-ILL
Subject: FW: In re: 10018373 Journal articles

-----Original Message-----

From: Ford, Vanessa
Sent: Monday, December 15, 2003 3:37 PM
To: STIC-Biotech/ChemLib
Subject: In re: 10018373 Journal articles

Carruthers, A., et al., Improvements of tension-type headache when treating wrinkles with botulinum toxin A injections, Headache, Oct. 1999;39:662-665, XP-001031356.

Vanessa L. Ford
Biotechnology Patent Examiner
Office: CM1 8DA16
Mailbox: CM1 8E12
Phone: 703.308.4735
Art Unit:1645

|255580

WEST Search History

DATE: Monday, December 15, 2003

<u>Set Name</u>	<u>Query</u>	<u>Hit Count</u>	<u>Set Name</u>
side by side			result set

DB=USPT; PLUR=YES; OP=ADJ

L16	L4 and l3	9	L16
L15	L14 and l9	26	L15
L14	torticollis	156	L14
L13	L12 and l9	62	L13
L12	dystonia	674	L12
L11	l9 and cosmetic	31	L11
L10	L9 and l4	8	L10
L9	l6 and (pure or purified)	359	L9
L8	l6 and l5	2	L8
L7	L6 and l4	8	L7
L6	l1 and l2	537	L6
L5	wrinkling	8733	L5
L4	hyperhidrosis	63	L4
L3	neurotoxin	1786	L3
L2	toxin	18946	L2
L1	botulinum	1017	L1

END OF SEARCH HISTORY

(FILE 'HOME' ENTERED AT 13:52:00 ON 15 DEC 2003)

FILE 'BIOSIS, CABAB, EMBASE, CAPLUS, LIFESCI, MEDLINE, SCISEARCH' ENTERED
AT 13:52:20 ON 15 DEC. 2003

L1 20899 S BOTULINUM TOXIN
L2 5306 S HYPERHIDROSIS
L3 4575 S WRINKLING
L4 668 S L1 AND L2
L5 34 S L1 AND L3
L6 1903422 S (PURE OR PURIFIED)
L7 825 S L6 AND L1
L8 2 S L7 AND L2
L9 1 S L7 AND L3
L10 509 S L4 AND TREAT?
L11 266 DUP REM L10 (243 DUPLICATES REMOVED)
L12 8 S L11 AND ANTIBODIES
L13 8 DUP REM L12 (0 DUPLICATES REMOVED)
L14 21 DUP REM L5 (13 DUPLICATES REMOVED)

(FILE 'HOME' ENTERED AT 13:52:00 ON 15 DEC 2003)

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L11 266 DUP REM L10 (243 DUPLICATES REMOVED)
L12 8 S L11 AND ANTIBODIES.
L13 8 DUP REM L12 (0 DUPLICATES REMOVED)
L14 21 DUP REM L5 (13 DUPLICATES REMOVED)
L15 0 S L14 AND ANTIBODIES

11 ANSWER 264 OF 266 BIOSIS COPYRIGHT 2003, BIOLOGICAL ABSTRACTS INC. on STN

DUPLICATE 114

AB The inhibitory action of **botulinum toxin** is not limited to the neuromuscular junction. The toxin also blocks the autonomic cholinergic fibres, including the sympathetic fibres to sweat glands. We have previously demonstrated that the toxin produces localized anhidrosis. To determine the dosage, pattern and duration of the anhidrotic effect of **botulinum toxin** and to test the efficacy of axillary injections, we further studied seven healthy volunteers. Two individuals had subcutaneous injections of **botulinum toxin** (20 mouse units, Dysport-Porton Products) in the dorsum of the hand. Five healthy volunteers had 15-50 U of **botulinum toxin** A (Botox) injected in one axilla. A circular area of complete anhidrosis on the dorsum of the hand was evident on day 2 and persisted for 11 months. By day 3, two of the axillae (injected with 50 U each) were totally dry and in one (injected with 30 U) the sweating was substantially reduced. The effect persisted for 6-8 months before wearing off. No effect was appreciated in two axillae (injected with 15 and 20 U). No significant side-effects were encountered. Subcutaneous injections of **botulinum toxin** causes chemodenervation of the sweat glands. In normal individuals axillary sweating can be abolished by 50 U of **botulinum toxin** A (Botox). The results offer a possible novel treatment for severe cases of axillary **hyperhidrosis**.

AN 1997:25001 BIOSIS

DN PREV199799324204

TI **Botulinum toxin. A possible new treatment for axillary hyperhidrosis.**

AU Bushara, K. O. [Reprint author]; Park, D. M.; Jones, J. C. [Reprint author]; Schutta, H. S. [Reprint author]

CS Dep. Neurol., Univ. Wis. Hosp. and Clin., 600 Highland Ave., Madison, WI 53792-5132, USA

SO Clinical and Experimental Dermatology, (1996) Vol. 21, No. 4, pp. 276-278. CODEN: CEDEDE. ISSN: 0307-6938.

DT Article

LA English

ED Entered STN: 15 Jan 1997

Last Updated on STN: 15 Jan 1997

L11 ANSWER 262 OF 266 BIOSIS COPYRIGHT 2003 BIOLOGICAL ABSTRACTS INC. on STN
AN 1997:430244 BIOSIS
DN PREV199799729447
TI Treatment of focal **hyperhidrosis** with
botulinum toxin.
AU Naver, H.; Aquilonius, S.-M.
CS Dep. Neurol., Univ. Hosp., Uppsala, Sweden
SO Journal of the Neurological Sciences, (1997) Vol. 150, No. SUPPL., pp.
S70-S71.
Meeting Info.: XVI World Congress of Neurology. Buenos Aires, Argentina.
September 14-19, 1997.
CODEN: JNSCAG. ISSN: 0022-510X.
DT Conference; (Meeting)
Conference; Abstract; (Meeting Abstract)
LA English
ED Entered STN: 8 Oct 1997
Last Updated on STN: 8 Oct 1997

L11 ANSWER 261 OF 266 EMBASE COPYRIGHT 2003 ELSEVIER INC. ALL RIGHTS RESERVED. on STN DUPLICATE 113

AB Primary axillary and palmar **hyperhidrosis** are common conditions which give rise to functional and emotional problems and may disturb professional and social life. For severe cases, in which topical agents, systemic anticholinergic agents and iontophoresis have been unsuccessful, surgical **treatment** is used. The method of choice is currently transthoracic endoscopic sympathectomy (TES). Serious complications such as peroperative cardiac arrest, chylothorax and haemothorax are rare. Common side effects include compensatory **hyperhidrosis**, gustatory sweating and dry hands. A pilot study of focal chemical denervation of sweat glands with **botulinum toxin** A was performed. Intracutaneous injections of **botulinum toxin** A into seven palms and eleven axillae of seven patients effectively eliminated **hyperhidrosis**. The advantage of our method over surgical denervation is that only the hyperactive sweat glands are denervated. As a result, compensatory **hyperhidrosis** may be avoided and the risk of surgical complications is eliminated.

AN 1998000078 EMBASE

TI The **treatment** of focal **hyperhidrosis** with **botulinum toxin**.

AU Naver H.; Aquilonius S.-M.

CS H. Naver, Department of Neurology, Uppsala University, Akademiska Sjukhuset, 751 85 Uppsala, Sweden

SO European Journal of Neurology, (1997) 4/SUPPL.2 (S75-S79).

Refs: 17

ISSN: 1351-5101 CODEN: EJNEFL

CY United Kingdom

DT Journal; Article

FS 008 Neurology and Neurosurgery
013 Dermatology and Venereology
037 Drug Literature Index
038 Adverse Reactions Titles
052 Toxicology

LA English

SL English

L11 ANSWER 259 OF 266 BIOSIS COPYRIGHT 2003 BIOLOGICAL ABSTRACTS INC. on STN
AN 1997:77717 BIOSIS
DN PREV199799384420
TI **Botulinum toxin for palmar hyperhidrosis.**
AU Naumann, Markus; Flachenecker, Peter; Broecker, Eva-B. [Reprint author];
Toyka, Klaus V.; Reiners, Karlheinz
CS Dep. Neurol. Dermatol., Julius-Maximilians-Univ., D-97080 Wuerzburg,
Germany
SO Lancet (North American Edition), (1997) Vol. 349, No. 9047, pp. 252.
ISSN: 0099-5355.
DT Article
LA English
ED Entered STN: 26 Feb 1997
Last Updated on STN: 26 Feb 1997

L11 ANSWER 258 OF 266 EMBASE COPYRIGHT 2003 ELSEVIER INC. ALL RIGHTS
RESERVED. on STN DUPLICATE 112

AB We performed a randomized double-blind study within-group comparison in 11 patients to study the effect of subcutaneous injections of botulinum A toxin in focal **hyperhidrosis** of the palms. A total dose of 120 mU (mouse units) of botulinum A toxin (Dysport.RTM.) was injected into six different sites on one palm, whereas the other was injected with sterile saline. Objective quantification of sweat production was performed using digitized ninhydrin-stained sheets. Three weeks after **treatment**, the mean reduction of sweat production in the botulinum A toxin-**treated** palms was 26% ($P < 0.001$), after 8 weeks 26% ($P = 0.002$) and after 13 weeks 31% ($P < 0.001$). Subjective assessment of sweat production by the patients using a visual analogue scale showed a 38% improvement in the botulinum A toxin-**treated** palms at 3 weeks ($P = 0.002$), 40% at 8 weeks ($P = 0.002$) and 38% at 13 weeks ($P = 0.002$). Neither the objective measurement nor the subjective rating showed a statistically significant reduction of sweating in the placebo-**treated** palms. Three patients reported reversible minor weakness of powerful handgrip after injection at the toxin-**treated** site, lasting between 2 and 5 weeks.

AN 97111991 EMBASE

DN 1997111991

TI Double-blind trial of botulinum A toxin for the **treatment** of focal **hyperhidrosis** of the palms.

AU Schnider P.; Binder M.; Auff E.; Kittler H.; Berger T.; Wolff K.

CS P. Schnider, Div. of Neurological Rehabilitation, Department of Neurology, University Clinic, Wahringer Gurtel 18-20, 1090 Vienna, Austria

SO British Journal of Dermatology, (1997) 136/4 (548-552).

Refs: 21

ISSN: 0007-0963 CODEN: BJDEAZ

CY United Kingdom

DT Journal; Article

FS 013 Dermatology and Venereology

037 Drug Literature Index

038 Adverse Reactions Titles

LA English

SL English

L11 ANSWER 255 OF 266 EMBASE COPYRIGHT 2003 ELSEVIER INC. ALL RIGHTS RESERVED. on STN

AB **Hyperhidrosis** is a source of embarrassment and can be a severe social problem. It may also signal a cutaneous disorder or other underlying disease. Ruling out secondary causes, paying attention to aggravating factors and giving simple topical **treatments**, such as aluminium chloride hexadhyrate or iontophoresis, will provide relief for most patients. This article describes the clinical features of the various forms of **hyperhidrosis**, discusses the simple topical **treatments** available, and outlines the options for the more stubborn cases.

AN 1998388742 EMBASE

TI Excessive sweating: Causes and what to do about it.

AU Isaacs F.

CS Dr. F. Isaacs, St George and Sydney Hospitals, Bondi Junction, NSW, Australia

SO Modern Medicine of Australia, (1998) 41/11 (30-34).

Refs: 6

ISSN: 1030-3782 CODEN: MMAUB7

CY Australia

DT Journal; General Review

FS 013 Dermatology and Venereology

037 Drug Literature Index

LA English

SL English

L11 ANSWER 251 OF 266 BIOSIS COPYRIGHT 2003 BIOLOGICAL ABSTRACTS INC. on STN
DUPLICATE 108

AB Background: Severe palmar **hyperhidrosis** is a chronic disease, resistant to conventional therapy. **Botulinum toxin** inhibits sweat production by blocking release of acetylcholine from presynaptic membranes. Objective: Our purpose was to evaluate the short- and long-term effectiveness of **botulinum toxin** therapy in **treatment** of palmar **hyperhidrosis**. Methods: Four patients with severe palmar **hyperhidrosis** were **treated** with subepidermal injections of **botulinum toxin**. Fifty injections, 2 mouse units each, were used in each palm. Regional nerve blocks of the median and ulnar nerves were performed before the procedure. Patients were observed for 12 months after **treatment**. Results: **Botulinum toxin** injections significantly reduced sweat production in the **treated** areas of the palms. Anhidrosis lasted for 12 months in one patient, 7 months in two patients, and 4 months in one patient. Mild weakness of the thumb lasting 3 weeks occurred in one patient. No other side effects were observed. Conclusion: **Botulinum toxin** provides an effective, safe, and long-lasting alternative therapeutic modality for **treatment** of severe palmar **hyperhidrosis**. Additional studies are needed for optimization of the technique.

AN 1998:170771 BIOSIS

DN PREV199800170771

TI **Botulinum toxin** therapy for palmar **hyperhidrosis**.

AU Shelley, W. B. [Reprint author]; Talanin, N. Y.; Shelley, E. D.

CS Div. Dermatol., Dep. Med., Med. Coll. Ohio, P.O. Box 10008, Toledo, OH 43699-0008, USA

SO Journal of the American Academy of Dermatology, (Feb., 1998) Vol. 38, No. 2 PART 1, pp. 227-229. print.

ISSN: 0190-9622.

DT Article

LA English

ED Entered STN: 6 Apr 1998

Last Updated on STN: 6 Apr 1998

L11 ANSWER 242 OF 266 EMBASE COPYRIGHT 2003 ELSEVIER INC. ALL RIGHTS
RESERVED. on STN
AN 1998380322 · EMBASE
TI Follow-up of patients with axillary **hyperhidrosis** after
botulinum toxin injection [9].
AU Heckmann M.; Schaller M.
CS Dr. M. Heckmann, Department of Dermatology, Ludwig-Maximilian University,
Frauenlobstrasse 9-11, 80337 Munich, Germany
SO Archives of Dermatology, (1998) 134/10 (1298-1299).
Refs: 5
ISSN: 0003-987X CODEN: ARDEAC
CY United States
DT Journal; Letter
FS 013 Dermatology and Venereology
037 Drug Literature Index
LA English

L14 ANSWER 17 OF 21 SCISEARCH COPYRIGHT 2003 THOMSON ISI on STN
AB Despite advances in techniques, aesthetic surgeons must realize that not every patient requires a complete forehead rejuvenation. This article discusses the contemporary armamentarium for forehead rejuvenation. Injection of **botulinum toxin** for glabella furrows is minimally invasive but only temporarily effective. Fat injection and fat grafts are useful for patients with a limited number of wrinkles and frown lines. Subcutaneous brow elevation provides direct correction of the forehead **wrinkling** by dividing the subcutaneous septae responsible for the furrows. Endoscopic techniques facilitate forehead rejuvenation with less morbidity and greater patient acceptance. Detailed descriptions of the spectrum of surgical options for forehead rejuvenation are included.

AN 97:366357 SCISEARCH

GA The Genuine Article (R) Number: WX597

TI Rejuvenation of the upper face - A logical gamut of surgical options

AU Michelow B J (Reprint); Guyuron B

CS 29017 CEDAR RD, LYNDHURST, OH 44124 (Reprint); CASE WESTERN RESERVE UNIV, SCH MED, DEPT SURG, CLEVELAND, OH 44106

CYA USA

SO CLINICS IN PLASTIC SURGERY, (APR 1997) Vol. 24, No. 2, pp. 199-&. Publisher: W B SAUNDERS CO, INDEPENDENCE SQUARE WEST CURTIS CENTER, STE 300, PHILADELPHIA, PA 19106-3399.
ISSN: 0094-1298.

DT Article; Journal

FS CLIN

LA English

REC Reference Count: 20

ABSTRACT IS AVAILABLE IN THE ALL AND IALL FORMATS

L14 ANSWER 18 OF 21 BIOSIS COPYRIGHT 2003 BIOLOGICAL ABSTRACTS INC. on STN
DUPLICATE 5

AB Objective: This study was conducted to evaluate the cosmetic use of **botulinum toxin** type A (Botox), which blocks the release of acetylcholine at the presynaptic neuromuscular junction leading to an irreversible, but temporary chemical denervation muscular paralysis and weakness. This produces a significant cosmetic improvement of **wrinkling** in the upper face due to hyperfunctional animation.
Method: A prospective clinical study representing our experience with this new technique is presented. Patient selection and evaluation, classification of animation lines, techniques, results and complications are discussed. In a 15-month period, 23 patients with seven anatomic sites were injected. Twenty-three patients had the lateral aspect and the inferior aspect of their squint lines injected, and 26 patients had their glabellar frownlines injected. Results: Significant improvement occurred to the average depth and length of the glabellar frownlines. The subjective improvement by the patients was also significant. Regarding the crow's feet, the lateral canthal lines showed more improvement than the inferior lateral canthal lines because the latter has a greater component of zygomaticus major and minor muscle, which contributes to the inferior lateral squint line. Conclusion: Botox is a safe, easy-to-use, effective modality for the temporary elimination of hyperfunctioning upper-facial muscles.

AN 1997:215225 BIOSIS

DN PREV199799521729

TI Cosmetic upper-facial rejuvenation with botulinum.

AU Ellis, David A. F. [Reprint author]; Tan, Andre K. W.

CS Toronto Centre Facial Cosmetic Surg., 167 Sheppard Ave. West, Toronto, ON M2N 1M9, Canada

SO Journal of Otolaryngology, (1997) Vol. 26, No. 2, pp. 92-96.
ISSN: 0381-6605.

DT Article

LA English

ED Entered STN: 22 May 1997

Last Updated on STN: 22 May 1997

L14 ANSWER 19 OF 21 EMBASE COPYRIGHT 2003 ELSEVIER INC. ALL RIGHTS RESERVED.

on STN

DUPLICATE 6

AB Purpose: External photography and subjective response were used to evaluate the use of botulinum A toxin to diminish glabellar kinetic folds. Methods: Eleven patients with glabellar folds and midline forehead wrinkling received one to four injections of 0.1 ml of 100 U/1 ml botulinum A toxin. The injections were given into the procerus or corrugator muscles or both. The number of injections corresponded to the wrinkle lines in each patient. The patients were examined and photographed just before the injections and at 7 to 10 days after the injections. Treatment efficacy was judged by photographic evaluation and by the patient's subjective evaluation of the effect of the treatment. Results: Photographic evaluation showed objective improvement in the glabellar wrinkling in 6 of 11 patients in relaxed facial position and in all 11 patients during contraction of the periocular muscles. Ten of the 11 patients reported satisfaction with their cosmetic results and indicated that they would choose to have the procedure done again. Conclusions: The results of this study suggest that botulinum A toxin is a safe and effective treatment for glabellar folds.

AN 96119890 EMBASE

DN 1996119890

TI The use of botulinum A toxin to ameliorate facial kinetic frown lines.

AU Foster J.A.; Barnhorst D.; Papay F.; Phaik Mae Oh; Wulc A.E.

CS Cleveland Clinic Foundation, 9500 Euclid Ave-A31, Cleveland, OH 44195, United States

SO Ophthalmology, (1996) 103/4 (618-622).

ISSN: 0161-6420 CODEN: OPHTDG

CY United States

DT Journal; Article

FS 011 Otorhinolaryngology

012 Ophthalmology

013 Dermatology and Venereology

037 Drug Literature Index

LA English

SL English

L14 ANSWER 20 OF 21 EMBASE COPYRIGHT 2003 ELSEVIER INC. ALL RIGHTS RESERVED.

on STN

DUPLICATE 7

AB Previous work on patients with muscular dystonia has shown that small intramuscular doses of **botulinum toxin** A eliminated hyperkinetic facial lines for approximately 6 months. The purpose of this study was to determine the efficacy of **botulinum toxin** A injections in eliminating facial wrinkles in aesthetic surgery patients who do not have muscular dystonia. Eleven healthy subjects were studied in a double-blind fashion. On both sides of the face, 0.2 cc of either normal saline or **botulinum toxin** A was injected into the forehead or into the periorbital wrinkles (crow's feet). Documentation of results was made by photographs taken of the patients during repose and during facial animation before and after injection. Assessment of facial wrinkles was done from a grading system in which the patient and the facial plastic surgeon were asked to judge the severity of the wrinkles on a scale from 0 to 3, with 0 reflecting no facial wrinkles and 3 reflecting severe facial wrinkling. Nine of 11 subjects injected with **botulinum toxin** A noted a significant improvement in the severity of their facial wrinkles in comparison with the side of the face injected with saline, with a rating improvement of 2 points. Two of 11 subjects noted a moderate improvement, with a rating improvement of 1 point. No patient injected with saline reported an improvement in the severity of the facial wrinkles on the control side. There were no serious complications. **Botulinum toxin** A is an efficacious method of nonsurgically eliminating facial wrinkles and may play a role in the cosmetic enhancement of the aging face.

AN 94240707 EMBASE

DN 1994240707

TI **Botulinum toxin** A for hyperkinetic facial lines:
Results of a double-blind, placebo-controlled study.

AU Keen M.; Blitzer A.; Aviv J.; Binder W.; Prystowsky J.; Smith H.; Brin M.

CS Atchley Pavilion, 161 Fort Washington Avenue, New York, NY 10032, United States

SO Plastic and Reconstructive Surgery, (1994) 94/1 (94-99).
ISSN: 0032-1052 CODEN: PRSUAS

CY United States

DT Journal; Article

FS 009 Surgery

037 Drug Literature Index

LA English

SL English

L14 ANSWER 21 OF 21 EMBASE COPYRIGHT 2003 ELSEVIER INC. ALL RIGHTS RESERVED.
on STN

DUPLICATE 8

AB Injury to the frontal or other facial nerve branches can result in an asymmetry that can be very distressful to both patient and surgeon. This is especially true following cosmetic procedures such as rhytidectomy. We propose a means to create temporary symmetry while awaiting the possible return of nerve function. Botulinum neurotoxin causes a muscle paralysis lasting for approximately 3 months, and it is well established as the preferred treatment for blepharospasm. A case is presented in which **botulinum toxin** type A was injected into the opposite functioning frontalis muscle of a patient with unilateral frontal nerve paralysis. The patient experienced satisfactory relief of the asymmetry caused by one-sided forehead wrinkling and brow elevation.

Botulinum toxin therapy should be considered for both temporary and permanent facial asymmetries due to facial nerve paralysis as well as spasm.

AN 89203356 EMBASE

DN 1989203356

TI **Botulinum toxin:** A treatment for Facial asymmetry caused by facial nerve paralysis.

AU Clark R.P.; Berris C.E.
CS United States
SO Plastic and Reconstructive Surgery, (1989) 84/2 (353-355).
ISSN: 0032-1052 CODEN: PRSUAS
CY United States
DT Journal
FS 034 Plastic Surgery
037 Drug Literature Index
LA English
SL English